REMARKS

Reconsideration of this application is respectfully requested. Claim 8 has been canceled without prejudice. Claim 1, 29, and 30 have been amended as discussed below. Claims 1 and 48 have been amended to replace the term "separate entities" with "separate layers." Support for this amendment is found at, for example, original claims 8 and 47, and paragraphs 26 and 27 of the published version of the present application (US 2008/0131503). In claims 2 and 3, the phrase "is in the form of" has been replaced with the phrase "comprises." Claim 48 has further been amended to delete both recitations of the phrase "as the active substance," and to correct an obvious grammatical error. Claim 49 has been added. Support for claim 49 can be found at, for example, in the original claims and Examples 6 and 7. Claims 1-7 and 9-49 are pending in this application. Because claims 11, 12, 19-23, 32-35 and 47 have been withdrawn from consideration, only claims 1-7, 9, 10, 13-18, 24-31, 36-46, and 49 are at issue.

Original claim 30 recited a solution solution of fenofibrate in a vehicle comprising polyethylene glycol 6000 (PEG 6000) and poloxamer 188. As discussed in the Declaration of Torben Elhauge submitted herewith, applicants have discovered that while the fenofibrate formulations containing polyethylene glycol and poloxamer have enhanced bioavailability, fenofibrate in the formulations is crystalline – i.e., the fenofibrate is not in a dissolved form.

Claim Objection

Claim 1 has been objected to for missing the article "a". The article "a" has been added to claim 1.

Claims 29, 30 and 48 have been objected because each recites "a solid solution." In the Examiner's view, solid solutions do not exist (*see* Office Action, p. 3). While applicants respectfully disagree with the Examiner, in order to expedite prosecution, the term "solid

solution" has been removed from claims 29 and 30. Applicant respectfully points out that claim 48 does not include the term "solid solution."

Indefiniteness Rejection

Claims 29 and 30 have been rejected under 35 U.S.C. § 112, second paragraph, as indefinite because, according to the Examiner, there is insufficient antecedent basis for the limitation "the active substance." Applicants respectfully point out that neither claim 29 nor claim 30 recites the limitation "the active substance." Accordingly, applicants respectfully request withdrawal of this rejection.

Anticipation Rejection

Claims 1-10, 13-16, 27-31, 36, 38-46 and 48 have been rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 6,534,808 ("Guivarc'h").

Independent claims 1 and 48 require that fenofibrate and an HMG-CoA reductase inhibitor be in separate layers. Guivarc'h does not disclose or suggest a composition for oral administration or a dosage form where fenofibrate and a HMG-CoA reductase inhibitor are in separate layers. Examples 5 and 6 of the present application disclose two-layer tablets of the presently claimed invention, and demonstrate that they are more stable than a simple mixture of granules of the two actives (*see*, *e.g.*, Example 6, p. 10 of US 2008/0131503). Accordingly, the presently claimed invention is novel over Guivarc'h, and applicants respectfully request withdrawal of this rejection.

Obviousness Rejection

Claims 1-10, 13-16, 24-31, 36, 38-46 and 48 have been rejected under 35 U.S.C. § 103(a) as obvious over Guivarc'h in view of U.S. Patent Publication No. 2005/0148594 ("Cink"), as evidenced by MeSH Descriptor Data, 2007. Claims 17, 18 and 37 have been rejected under 35 U.S.C. § 103(a) as obvious over Guivarc'h in view of Cink, as evidenced by MeSH Descriptor Data, 2007, as applied to claims 1-10, 13-16, 24-31, 36 and 38-46 above, and further in view of U.S. Patent Publication No. 2004/0023919 ("Ohsawa").

None of the cited references disclose or suggest a stable composition containing both fenofibrate and an HMG-CoA reductase inhibitor. As shown by Example 6, simvastatin is not stable in the presence of the fenofibrate composition of the present invention. In particular, 3.9% of the simvastatin converted to its corresponding hydroxy acid when simvastatin granules were mixed with fenofibrate granules, tabletted, and stored for 1 month at 25°C and 60% relative humidity. In contrast, when the simvastatin and fenofibrate granules were incorporated into separate layers in a tablet, only 0.2% of the simvastatin converted to its hydroxy acid under the same conditions. This result is surprising and unexpected, especially in view of the fact that neither Cink nor Guivarc'h teaches a tablet with each layer comprising a separate active ingredient (*i.e.*, one layer with fenofibrate, one layer with the HMG–CoA reductase inhibitor).

The Examiner contends that Cink teaches formulations containing tromethamine (also known as 2-amino-2-(hydroxymethyl)-1,3-propanediol) with fenofibrate and atorvastatin. Pending claim 26 recites that the second composition contains atorvastatin and 2-amino-2-(hydroxymethyl)-1,3-propanediol. Cink does not teach tromethamine as a stabilizer for a statin in a composition comprising fenofibrate and a statin (HMG–CoA reductase inhibitor) in separate layers. Cink teaches compounds comprising the tromethamine salt of fenofibrate (*see*, *e.g.*, Example 27). Since fenofibrate and the HMG–CoA reductase inhibitor are present in separate layers in the presently claimed composition, tromethamine in the fenofibrate layer would not interact with the HMG-CoA reductase inhbitor (the statin).

According to the Examiner, Ohsawa teaches that ascorbic acid co–administration with atorvastatin reduces total cholesterol levels. Pending claims 17 and 18 call for a stabilizer capable of providing a microenvironment for atorvastatin having a pH of at least about 5 or 6. A 5% solution of ascorbic acid has a pH of about 2.5. Therefore, ascorbic acid is not a stabilizer that can provide a microenvironment for atorvastatin having a pH of at least about 5 or 6. Agents capable of establishing such an environment are given at paragraph [0039] of the published version of the present application (US 2008/0131503). Ascorbic acid is not recited in this section of the specification.

For the foregoing reasons, the pending claims are non-obvious over the cited references, alone or in combination. Accordingly, applicants respectfully request withdrawal of this rejection.

CONCLUSION

Based on the preceding amendments and arguments, the pending claims are believed to be in condition for allowance, which is earnestly solicited. If there are remaining issues that the Examiner believes could be addressed by conducting an interview or entering an Examiner's Amendment, the Examiner is cordially invited to contact the undersigned agent to discuss such issues.

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Respectfully submitted,

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